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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,401	01/16/2002	Alfred Pollak	7126-2	8318

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NEW YORK, NY 10036

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

ML

Office Action Summary

Application No.

09/913,401

Applicant(s)

POLLAK ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 and 33-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

COMMENT/NOTE

1. The previous office action is moot in view of the action below.

Note: Claims 1-31 and 33-49 are pending.

LACK OF UNITY

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous compositions possible comprising a metal support, ligand, and targeting molecule, and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I. Claims 1-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is gold; the ligand is NxS_4-x wherein $x = 0$; targeting moiety is SEQ ID No. 1; the disease is an oncological disease; and the disease is assessed by positron emission tomography.

Group II. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is silver; the ligand is NxS_4-x wherein $x = 1$; targeting moiety is SEQ ID No. 2; the disease is a neurological disease; and the disease is assessed by nuclear magnetic resonance imaging.

Group III. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal

support is copper; the ligand is NxS_4-x wherein $x = 2$; targeting moiety is SEQ ID No. 3; the disease is an inflammatory disease; and the disease is assessed by single photon emission computed tomography.

Group IV. Claims 1-15, 17-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Tc; the ligand is NxS_4-x wherein $x = 3$; targeting moiety is bombesin 7-14; the disease is an infection; and the disease is assessed by ultrafast x-ray computed tomography.

Group V. Claims 1-15, 17-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Re; the ligand is NxS_4-x wherein $x = 0$; targeting moiety is a dopamine receptor; the disease is an oncological disease; and the disease is assessed by positron emission tomography.

Group VI. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Mn; the ligand is NxS_4-x wherein $x = 1$; targeting moiety is a serotonin receptor; the disease is a neurological disease; and the disease is assessed by digital subtraction angiography.

Group VII. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Fe; the ligand is NxS_4-x wherein $x = 2$; targeting moiety is a nicotinic receptor; the disease is an inflammatory disease; and the disease is assessed by positron emission tomography.

Group VIII. Claims 1-15, 17-21, 24-31, 33-42, and 45-49 (in-part), drawn to product, methods of making the product, and uses of a product wherein the metal support is Ni; the ligand is NxS_4-x wherein $x = 3$; targeting moiety is a GABA receptor; the disease is an infection; and the disease is assessed by single photon emission computed tomography.

Group IX. Claims 43 and 44, drawn to products a method of preparation of a support surface for manufacturing a complex forming metal labeled agent.

Note: Each of Groups I – VIII are directed to a composition comprising a metal support, ligand, and targeting moiety; a method of generating a complex using the composition; a pharmaceutical composition comprising the composition; a method of detecting the presence or assessing the severity of a disease; a method of radiotherapy of a disease, disorder, or abnormal physical state; a method of detecting/assessing a disease using a specific technique; and a kit comprising the composition.

3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, *this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed.* Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and the examiner will endeavor to group the same.

Art Unit: 1618

4. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the groups of inventions defined in the claims lack a significant metal support-ligand-target combinations qualifying as the special technical feature that defines a contribution over the prior art. The groups of inventions claimed contain a metal support which does not define a contribution over the prior art. The targeting moiety and ligand combinations which are conjugated to the metal support vary extensively and when taken as a whole result in vastly different complexes. In addition, the diseases which the complexes may be used vary extensively. In particular, the complexes may be used for assessing the severity of oncological diseases, neurological diseases, inflammatory disease, and infections. Also, the diseases may be assessed vary extensively. For example, possible methods of assessing or detecting the presence or severity of the disease include, positron emission tomography, nuclear magnetic resonance imaging, scintigraphy, single photon emission computed tomography, perfusion contrast echocardiography, ultrafast x-ray computed tomography, and digital subtraction angiography. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

5. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1618

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

July 21, 2005